DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018066/S-020

SUPPLEMENT APPROVAL

Chattem, Inc.
Attention: David Schilling
Associate Director, Regulatory Affairs
1715 West 38th Street
Chattanooga, TN 37409

Dear Mr. Schilling:

Please refer to your Supplemental New Drug Application (sNDA) dated October 19, 2012, received October 22, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Unisom® SleepTabs® (doxylamine succinate) tablets, 25mg.

We acknowledge receipt of your amendments dated February 28, March 19, April 11, and August 19, 2013.

The August 19, 2013, submission constituted a complete response to our April 19, 2013, action letter.

This "Prior Approval" supplemental new drug application proposes to add the Warning "**Do not use** in children under 12 years of age" and to update the product's shelf presence.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the submitted labeling (8-count, 16-count, 32-count, and 48-count outer carton labels submitted August 19, 2013 and the 16-count immediate container (blister card) label submitted on February 28, 2013), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. Even though no revisions were made to the child-resistant immediate container (blister card) used with the 8-count, 32-count, and 48-count SKUs, submit the child-resistant immediate container (blister card) as part of the FPL for this supplement in order to maintain a record of the complete labeling.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 018066/S-020**" Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Daniel Reed, Regulatory Project Manager, at (301) 796-2220.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
09/12/2013